COLORADO STATE BOARD OF PHARMACY July 16, 2009

Minutes

The Colorado State Board of Pharmacy meeting was convened by President Paul Limberis, R.Ph., at approximately 8:30 a.m. on Thursday, July 16, 2009 at 1560 Broadway, Conference Room 1380, Denver, CO 80202. Notice of this meeting was given in accordance with Division of Registrations Policy Number 80-17.

Board members attending were: Mary K. Arceneaux, R.Ph., Jeannine G. Dickerhofe, R.Ph. (by phone), Rich Doyle, R.Ph., Leonard Hierath, P.E., Paul Limberis, R.Ph., and Averil Strand, R.N.

Staff members attending were Wendy Anderson, R.Ph., Program Director; Chris Gassen, R.Ph., Chief Inspector; Mark O'Neill, R.Ph., Inspector; and Susan Martin, R.Ph., Inspector. Also present was Jo Kaye, Assistant Attorney General to advise the Board.

APPROVAL OF MINUTES

The Board approved the minutes from the May 14, 2009, June 12, 2009, and June 29, 2009 meetings as amended.

ADDITIONS TO THE AGENDA

Xttrium Laboratories, Inc.

Proposed changes to Rule 5.01.31

Kevin Potts, #16983

APPEARANCES

None

HEARINGS

None

REPORTS

President's Remarks

Mr. Limberis discussed the National Association of Boards of Pharmacy ("NABP") 105th Annual Meeting which took place in Miami, FL, May 16 – May 19, 2009. Jeannine Dickerhofe served as the Board's voting delegate this year. Mr. Limberis also attended.

Six Resolutions passed in addition to a Recognition Resolution. These resolutions are as follows:

- 1. NABP convene a task force for Electronic Prescribing Software Standards and Data Storage.
- 2. NABP continue efforts to address over-prescribing and excessive use of controlled substances and other prescription medications.

- 3. Language be added to the Model Act "A face-to-face physical examination is not required to establish a valid patient-practitioner relationship if:
 - a) The prescribing practitioner is issuing a prescription or dispensing a legend drug in accordance with expedited partner therapy in the management of sexually transmitted diseases guidance document issued by the United States Centers for Disease Control and Prevention: or
 - b) The prescription, administration, or dispensing is through a public health clinic or other distribution mechanism approved by the state health authority in order to prevent, mitigate or treat a pandemic illness, infectious disease outbreak, intentional or accidental release of a biological, chemical or radiological agent.
- 4. NABP Executive Committee develop and submit a proposed amendment to define the term "administrative officer."
- 5. NABP assist and encourage state boards of pharmacy to evaluate and approve training programs for pharmacy technicians licensed or registered in their states. In addition, NABP convene a task force to review existing state requirements for educational and training programs and national accrediting organizations to recommend national standards for technician education and training programs to be considered by boards of pharmacy.
- 6. NABP commission a task force to review existing prescription drug monitoring programs and recommend standards or model rules.

One Resolution failed. This was intended for NABP to research the development of an Ethics Course for licensees and to require that pharmacists complete an ethics course as part of mandatory CE requirements.

The newly elected officers of the NABP Executive Committee are President-elect William Winsley from the Ohio State Board of Pharmacy, Treasurer Malcom Broussard, Executive Director of the Louisiana State Board of Pharmacy, Three year board member Joseph Adams, member of the Louisiana State Board of Pharmacy, and Cathryn Lew, member of the Oregon State Board of Pharmacy. Gary Schnabel, Executive Director of the Oregon State Board of Pharmacy assumed the office of NABP president.

Program Director's Report

Ms. Anderson told the members that a new board member roster and a 2010 Board meeting schedule had been placed in their folders. She announced that Mr. Limberis had been reappointed for an additional four-year terms which will expire on July 1, 2013. She announced that the Board's next meeting on August 20, 2009 would be held at Regis University School of Pharmacy. Directions would be included in the members packets which are mailed out in advance of the meeting.

The Board then considered Board Policy 10-9. After due consideration, the Board approved the policy as revised.

The Board considered proposed changes to Rule 6.00.20(f), (Drug Therapy Management Filing Requirements). After due consideration, the Board moved the proposed changes to hearing.

The Board then considered proposed changes to Policy 20-11, "Board Criteria to Identify Wholesaler Applicants which Require board Review). After due consideration, the proposed changes were approved.

Colorado Pharmacists Society (CPS) - Rich Doyle, RPh

The Annual Summer Meeting was held on June 26-28, 2009 in Copper Mountain, Colorado. Eleven hours of continuing education ("CE") was offered. The education programs included a new drug update, programs that focused on quality assurance, improving disease state management skills and helping to maintain continuing competency in drug therapy and pharmacy law. The business session included the State of the Society Report which is posted on the CPS website, www.copharm.org. During the business session, the CPS Board of Directors election results were announced and are as follows: Andrew Bjork will represent the Health-System Pharmacy Management, Mary Newell will represent Chain Pharmacy Non-Management. Laura Hansen is the At-Large Representative. During the awards and installation dinner, Mary Newell, was presented with the Pharmacist of the Year Award. Incoming President Carole Shelton received the McKesson Leadership Award and the NCPA Leadership Award. Randy Knutsen was installed as the President-Elect and Carole Shelton was installed as President. Her inaugural address is posted on the CPS website.

The next major CE Event is the 2009 CPS Annual Fall Meeting, September 24-26, 2009 at the Radisson Denver Stapleton Plaza. This year, the meeting will be held in conjunction with the Colorado Society of Parenteral and Enteral Nutrition. The Friday program on September 25th will provide education programs for health-system pharmacists and the Saturday program will be for community/retail pharmacists. Twelve hours of ACPE approved continuing education will be provided and details will be posted on the CPS website the end of this week.

Planning has begun for the 2010 Winter CE Seminar, January 10-13, 2010 in the Avon Westin. Fifteen hours of CE programming will be offered and details will be on the CPS website.

Governor's Expert Emergency Epidemic Response Committee (GEEERC) - Paul Limberis, RPh

The GEEERC met on Thursday, July 2, 2009.

The meeting primarily involved discussion of the Colorado Department of Public Health and Environment's ("CDPHE") response to the H1N1 outbreak in April 2009. It was noted that in general Colorado acted well as a Public Health Department. The daily messaging that occurred with the local health departments, while not always appearing to have been most efficient, was helpful to those at the local level. The communication summaries that followed were helpful as well, especially for those that were not able to attend the conference calls. It was also felt that the Centers for Disease Control and Prevention "CDC " waited two days longer on school closures and that travel advisory for Mexico should have been warranted earlier. There was also no real plan for migrant workers living in dormitories. The Co-Pharm network proved to be very time intensive and the data was inaccurate after one day. Of the 23,000 doses of Tamiflu accounted for on one Friday, almost all were gone by the following Sunday. This showed the inappropriate prescribing of Tamiflu that was occurring.

The Strategic National Stockpile of Tamiflu and Relenza arrived on Wednesday, April 29, 2009. The system worked very well with the delivery to the Receipt Store Site ("RSS"), dividing the doses for all areas, and shipping product out on the three routes – South, Central, and North. Everything was in position by Friday, May 1, 2009.

For the fall of 2009, there are plans for all citizens to be able to obtain two doses of the vaccine. Plans will need to be made for large amounts of vaccine to be shipped. It is still not defined whether the vaccine will be shipped out through the Strategic National Stockpile ("SNS") system or that product will be delivered directly to providers. Distribution of the vaccine will definitely occur. However, the timeline is unclear at present.

Intern & School Relations - Jeannine Dickerhofe, RPh

Lane Brunner, the Dean of Regis University School of Pharmacy reported that the school had been approved by the American Council of Pharmacy Education ("ACPE") for precandidate status. The first class will consist of fifty students. Classes will begin on August 24, 2009.

Legislation - Jeannine Dickerhofe, RPh.

None.

Rules - Rich Doyle

None.

Inspectors

Michelle Woods, Unlicensed

After due consideration of the available information, the Board voted to send a Cease and Desist Order to Ms. Woods for practicing as a pharmacy intern without a license.

The board voted to initiate complaints against Benjamin Jimerson, RPH 12429, and Walgreen Pharmacy #07138 (PDP 658), for allowing an unlicensed pharmacy intern to practice at the pharmacy.

Daniel Edmisten, RPH 15052

After due consideration of the available information, the Board voted to initiate a complaint against Mr. Edmisten's license.

Kevin Potts, RPH 16983

After due consideration of the available information, the Board voted to initiate a complaint against the license of Mr. Potts and order him to undergo an evaluation with Peer Assistance Services.

OLD BUSINESS

Stipulations

Dewey, Robert L., RPH 12643

The Board reviewed an Agenda Memorandum from Tia Johnson, Complaint/Licensing Analyst, concerning Mr. Dewey's request for discharge from the terms of his Stipulation and Final Agency Order. After due consideration of the available information, the Board denied release.

Hogan, Roger M., Jr., RPH 8957

The Board reviewed an Agenda Memorandum from Mr. Gassen concerning Mr. Hogan's request for discharge from the terms of his Stipulation and Final Agency Order. After due consideration of the available information, the Board released Mr. Hogan from his stipulation.

Marks, Michael L., Jr., RPH 15577

The Board reviewed an Agenda Memorandum from Ms. Johnson concerning Mr. Mark's request for discharge from the terms of his Stipulation and Final Agency Order. After due consideration of the available information, the Board released Mr. Marks from his stipulation.

McGinnity, Leonard D., RPH 9625

The Board reviewed an Agenda Memorandum from Ms. Johnson concerning Mr. McGinnity's request for discharge from the terms of his Stipulation and Final Agency Order. In addition, the Board reviewed the most recent report from his practice monitor. After due consideration of the available information, the Board tabled action on his request. The Board, however, did vote to initiate a complaint against Mr. McGinnity's pharmacist license regarding violations detailed in the most recent report from his practice monitor.

Paynter, Christien T., RPH 17834

The Board reviewed an Agenda Memorandum from Ms. Johnson concerning Mr. Paynter's request for discharge from the terms of his stipulation and final agency order. After due consideration, the Board released Mr. Paynter from his stipulation.

Direct Pharmacy Services, OSP 5683

The Board learned that Directed Pharmacy Services had entered into a Stipulation and Final Agency Order with the Board effective June 11, 2009. One of the terms of this order required the pharmacy to pay a fine with a surcharge of 15%. As of the date of the Board meeting, Direct Pharmacy Services, had not remitted payment. After due consideration the Board voted to suspend the license of the pharmacy if the fine has not been remitted by July 23, 2009.

Complaints

Coram Specialty Infusion Services, PDO 37-24

2009-2224

The Board tabled action on this matter. However, it voted to initiate a complaint against the pharmacist license of Beverley Ornes, RPH 12044.

NEW BUSINESS

Complaints

Atlantic Biologicals Corp., WHO 7598

2009-3892

A motion was made, seconded, and carried to dismiss the case as being without merit. The Board did vote, however, to issue a Letter of Guidance to the Respondent.

Caremark Kansas Specialty Pharmacy, OSP 5155

2009-3758

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Eflin, Stephanie L., RPH 17541

2009-3704

Mary Arceneaux recused.

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Fallik, Aaron P., RPH 17129

2009-3731

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

The Board did direct staff to send correspondence to Mr. Fallik notifying him that future non-compliance with his Stipulation and Final Agency Order will result in his pharmacist license being suspended until which point he comes into compliance.

Franck's Lab, Inc., OSP 5177,

2009-3707

After due consideration, the Board voted to table action pending the outcome of the matter in the State of Florida.

I.T.C. Compounding & Natural Wellness Pharmacy, PDO 37-18 2009-3699

A motion was made, seconded, and carried to dismiss the case as being without merit.

Keith, Lana S., RPH 16950

2009-3705

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

King Soopers Pharmacy #06, PDO 24-33

A motion was made, seconded, and carried to dismiss the case as being without merit.

Lee, Connie H., RPH 13640

A motion was made, seconded, and carried to dismiss the case as being without merit.

Liden, Jon Daniel, RPH 14705

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

Mattson, Mary M., RPH 10019

2009-3875

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Meyer, Dawn R., RPH 14762

2009-3700

A motion was made, seconded, and carried to dismiss the case as being without merit.

Owens & Minor Distribution, Inc., WHI 6008

2009-3258

After due consideration of the available information, the Board voted to refer the case for discipline.

Patterson Logistics Services, Inc., WHI 6058

2009-3408

After due consideration of the available information, the Board voted to refer the case for discipline.

Summit View Pharmacy, PDO 501

2009-3473

A motion was made, seconded, and carried to dismiss the case as being without merit.

The Compounding Center Pharmacy, Inc., WHO 7599.

2009-3901

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Walgreen Pharmacy #6283, PDO 104-65

2009-3553

After due consideration of the available information, the Board voted to refer the case for discipline.

Walgreen Pharmacy #5262, PDO 24-117

2009-3517

After due consideration of the available information, the Board voted to refer the case for discipline.

Walgreen Pharmacy #5645, PDO 82-8

2009-3817

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Weber, Pamela S., RPH 17048

2009-3815

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Skorey, Vincent R., RPH 17189

2009-3816

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Bergan, Stephen R., RPH 10024

2009-3814

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Wierimaa, Jacqueline R., RPH 17001

2009-3322

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Gruszynski, Jason J., RPH 15975

2009-3321

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

LICENSING

Other Outlets, New

The Board approved the registration of 0 new other outlets.

Prescription Drug Outlets, New (In-State)

The Board approved the registrations of 4 new in-state prescription drug outlets.

Prescription Drug Outlets, New (Out-of-State)

The Board approved the registrations of 16 new nonresident prescription drug outlets.

Manufacturers, New

The Board approved the registrations of 0 new manufacturers.

Limited Licenses, New

The Board approved the registrations of 0 new limited licenses.

Wholesalers, New (In-State)

The Board approved the registrations of 0 new in-state Wholesalers.

Wholesalers, New (Out-of-State)

The Board approved the registrations of 53 new out-of-state Wholesalers.

Licensure by Examination and Score Transfer

The Board ratified the licensure of 12 applicants for licensure.

Licensure by License Transfer

The Board ratified the licensure of 24 applicants seeking licensure through license transfer. It was noted that these licensees met all of the requirements for licensing under the provisions of section 12-22-116, C.R.S.

LICENSURE ISSUES

Guardian Laboratories, Out-of-State Wholesaler Applicant

After review of the available information, the Board voted to approve the registration.

Xttrium Laboratories, Inc., Out-of-State Wholesaler Applicant

After review of the available information, the Board voted to table action on the application pending additional information..

MISCELLANEOUS

Correspondence, etc.

Meeker Drug, PDO 86-2(cancelled)

The Board considered an agenda memorandum from Mr. Gassen. After due consideration, the Board voted to send correspondence concerning Meeker's Drugs drug destruction to the Rio Blanco County Health Department.

Valley-Wide Health Systems Other Outlets & Petition to Reduce Visitation Schedule After due consideration, the Board denied the request.

Jacob Gonzales, RPH 16590

After due consideration of the available information, the Board noted the information, deciding that no further information was necessary.

King Soopers Pharmacy #133, PDO 564

The Board tabled action on this item pending additional information.

Brent Stein, RPH 18223 and Good Day Pharmacy, PDO 56-4

After due consideration of the available information, the Board noted the information deciding that no further action was necessary.

Poudre Valley Hospital & Medical Center of the Rockies

The Board considered the hospitals' requests and proposed changes to regulation 5.01.31 from Board staff. After due consideration of the available information, the Board voted to refer the proposed changes to regulation 5.01.31 to hearing.

Mercy Regional Medical Center & CRS 12-22-102(32.5)

The Board considered this request and directed staff to inform the hospital that the Board would be doing rulemaking on regulation 5.01.31 to address the concerns.

Regis University & Proposed Compounding/Dispensing Area

After due consideration of the available information, the Board voted to deny the request.

Correspondence from Sandoz, US Generics

The Board noted the information.

Missouri Compounding Drug Testing Report

The Board noted the information.

Regis University Health Center, Request for Change to Visitation Schedule

The Board tabled action on the request pending additional information.

2007 Referral to the Colorado State Board of Medical Examiners

The Board noted the action.

FDA News Release

The Board noted the information detailing stolen vials of insulin.

NABP Position Paper on the Continued Proliferation of Rogue Internet Drug Outlets The Board noted the report.

NABP State News Roundup

The Board noted the May 2009 information.

NABP Technician Examination Update, June 11, 2009

The Board noted the information.

Royal Pharmaceutical Society, News Release, May 14, 2009

The Board noted that pharmacy technicians are going to be regulated in Great Britain.

EXECUTIVE SESSION

Board President Paul Limberis moved that the Board enter into executive session as authorized by CRS 24-6-402 subsection (3)(a) roman (III) to discuss matters which are required by law to be kept confidential. Specifically, the provisions of law requiring these matters to be kept confidential are:

CRS 24-6-402 subsection (3)(a) romans (II) and (III), and section 13-90-107(b), which protect as confidential communications with counsel that are matters of pending or imminent litigation, or are otherwise subject to the attorney-client privilege, and CRS 25-1-1201 et sequitor, which protects the confidentiality of information pertaining to individual medical records.

The motion was unanimous.

The Board discussed all items referred to it earlier in the meeting as well as matters confidential by law.

Open Session

2009-2937

A motion was made, seconded, and carried to dismiss the case as being without merit.

The Board voted to initiate a complaint against Walgreen Pharmacy #3586 for failing to maintain records of prescriptions returned to stock.

2009-3754

After due consideration of the available information, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act and Board regulations.

The Board voted to initiate a complaint against Walgreen Pharmacy #3589.

The Board voted to initiate a complaint against Benjamin Glennon, RPH #17237.

2009-3329

A motion was made, seconded, and carried to dismiss the case as being without merit.

The Board voted to send a letter of guidance to Safeway Pharmacy #1479 (PDO 128-14) discussing the pharmacy's procedures for delivering prescriptions to consumers.

The Board voted to deny applicant PR-18-147 into the Pharmacy Peer Health Assistance Diversion Program.

The Board voted to admit applicant PR09-166 into the Pharmacy Peer Health Assistance Diversion Program.

The Board voted to allow participant PR-09-163 to return to practice.

Robert Governski, RPH #14225

Mary Arceneaux recused.

The Board voted to initiate a complaint against Mr. Governski for failing to comply with his contract with the Rehabilitation Evaluation Committee ("REC"). In addition, the Board voted to summarily suspend Mr. Governski's pharmacist license pursuant to CRS 12-22-605 if he fails to come into compliance with his REC contract by July 27, 2009.

Mary Denise Sneed-Croop, RPH 11843

The Board voted to initiate a complaint against Ms. Sneed-Croop's pharmacist license for failing to comply with her Rehabilitation Evaluation Committee contract.

Scott Brierton, RPH 13440

The Board voted to suspend Mr. Brierton's pharmacist license for failing to comply with his Stipulation and Final Agency Order should he fail to relinquish his pharmacist license by July 23, 2009.

ADJOURNMENT

The Board adjourned at approximately 5:30 p.m.

Approved by Paul Limberis, R.Ph., President Date: August 20, 2009